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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/731,739 | 12/10/2003 | John P. Carulli | 032796-217 | 5366 |
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| 21839 | 7590 | 04/20/2006 |
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| EXAMINER |
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QIAN, CELINE X

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding..

| | | | |
|------------------------------|---|---------------------------------------|--|
| Office Action Summary | Application No. 10/731,739 | Applicant(s) CARULLI ET AL. | |
| | Examiner Celine X. Qian Ph.D. | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,14,15,22-27,43,44 and 75-80 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4-8,14,15,22-27,43,44 and 75-80 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1, 2, 4-8, 14, 15, 22-27, 43, 44, 75-80 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 1, 2, 4-8, drawn to an isolated nucleic acid sequence of SEQ ID NO:1, classified in class 536, subclass 23.1.

Group II, claims 14 and 15, drawn to a method for identifying a protein involved in bone modulation comprising identifying a protein has an expression level different in a first host comprising Zmax1 gene when compared to a second host comprising the HBM gene, classified in class 530, subclass 350.

Group III, claims 22, 23 and 80, drawn to a method for identification of a candidate molecule involved in bone modulation by identifying molecules that binds to or inhibit the binding of molecules to nucleic acid sequences SEQ ID NO:1 and SEQ ID NO:2, classified in class 530, subclass 387.1.

Group IV, claims 24 and 25, drawn to a method of pharmaceutical development for treatment of bone development disorders by identifying a molecule that binds to the amino acid sequence of SEQ ID NO: 2, classified in class 424, subclass 130.1.

Group V, claims 26 and 27, drawn to a method of pharmaceutical development for treatment of bone development disorders by obtaining a first and second cell free extract contains Zmax1 gene/protein, and HBM gene/protein respectively, identifying a molecule that causes the first cell free extract to exhibit a

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characteristic feature of the second cell free extract, classified in class 435, subclass 6.

Group VI, claims 26 and 27, drawn to a method of pharmaceutical development for treatment of bone development disorders by obtaining a first and second cell that contain Zmax1 gene/protein, and HBM gene/protein respectively, identifying a molecule that causes the first cell to exhibit a characteristic feature of the second cell, classified in class 435, subclass 325.

Group VII, claims 26 and 27, drawn to a method of pharmaceutical development for treatment of bone development disorders by obtaining a first and second animal that contain Zmax1 gene/protein, and HBM gene/protein respectively, identifying a molecule that causes the first animal to exhibit a characteristic feature of the second animal, classified in class 800, subclass 8.

Group VIII, claims 43 and 44, drawn to a method for treating bone development disorders comprising administering a molecule that binds to the nucleic acid sequence of SEQ ID NO:1 to a patient in need thereof, classified in class 536, subclass 24.5.

Group IX, claims 75-79, drawn to an isolated nucleic acid of at least 15 contiguous nucleotides that comprises a polymorphic site, classified in class 536, subclass 24.31.

The inventions are distinct, each from the other for following reasons.

Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation,

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and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to nucleic acid having different length and sequences. Each has different effects and modes of operation, the nucleic acid of Group I encodes a protein product, wherein the nucleic acid of Group IX maybe used as probes for different polymorphic sites. Therefore, the invention of Group I and IX are patentably distinct from each other.

Inventions II-VIII are directed to unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the claimed method are directed to methods that require different starting material and modes of operation. The methods are not capable of being use together, each has a different design, and comprises distinct steps to achieve different purposes. Therefore, the invention of Groups II-VIII are patentably distinct from each other.

The invention of Groups I and IX are patentably distinct from the invention of Groups II-VIII because they are drawn to methods and products that are not related. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of Groups II-VIII do not require the use of products of Groups I and IX, whereas the products of Groups I and IX can be used in methods other than those of Groups II-VIII. For example, the method for identifying a protein that modulating bone development does not require the isolated nucleic acid of Group I, and the nucleic acid of Group I can be used to express a protein in vitro. Therefore, the invention of Groups I and IX are patentably distinct from the invention of Groups II-VIII.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. A search of the subject matter of one invention would not be co-extensive with a search of the other invention, and therefore the search would be burdensome. Each invention is capable of supporting a separate patent.

Groups I and IX are comprised of multiple inventions which are the products drawn to different and distinct sequences which do not render obvious each other and thus are patentably distinct. If any of Groups I or IX are elected, applicants must elect a single invention which is the product drawn to one specific sequence to which the claims will be restricted. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

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specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

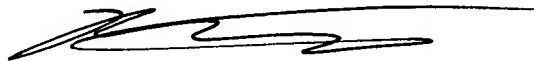
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Celine X Qian', with a long horizontal line extending to the right.